SEP - 5 2001

K010935

510(k) Summary
for
BriteSmile Barrier Material

1. SPONSOR

BriteSmile, Inc.
490 Wiget Lane
Walnut Creek, CA 94598

Contact Person: Stephen H. Miller
Telephone: 925-279-2868

Date Prepared: March 27, 2001

2. DEVICE NAME

Proprietary Name: BriteSmile Barrier Material
Common/Usual Name: Gingival isolation material
Classification Name: Rubber Dam

3. PREDICATE DEVICE

OpalDam
Ultradent Products, Inc.
K971284

4. INTENDED USE

The BriteSmile Barrier Material is intended to protect soft tissue adjacent to teeth during teeth-whitening procedures.

5. DEVICE DESCRIPTION

The BriteSmile Barrier Material is a monomer-free, photopolymerizable, opaque, light-reflective gel that is applied directly onto the gingival surfaces in order to protect the soft tissue from exposure to (1) oxidizing agents in tooth whiteners; and (2) high intensity blue light during light-activated tooth whitening procedures.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The BriteSmile Barrier Material has the same intended use, same mechanism of action, and similar material specifications as compared with the OpalDam material. Testing to support substantial equivalence included biocompatibility testing and performance testing. The biocompatibility testing demonstrated that the BriteSmile Barrier Material is not cytotoxic, does not have the potential for sensitization, and does not cause skin irritation. The performance testing demonstrated that the BriteSmile Barrier Material has a lower peak exotherm during curing as compared with OpalDam, and cures to a flexible, rubbery consistency that resists deformation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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BriteSmile, Incoporated
C/O Ms. Sheila Hemeon-Heyer
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K010935
Trade/Device Name: BriteSmile Barrier Material
Regulation Number: 872.6300
Regulatory Class: I
Product Code: EIE
Dated: July 12, 2001
Received: July 16, 2001

Dear Ms. Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010935

Device Name: BriteSmile Barrier Material

Indications for Use:

The BriteSmile Barrier Material is intended to protect soft tissue adjacent to the teeth during teeth-whitening procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010935

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)